K003583

JAN 17 2001

510 (k) Summary

This Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter: TRACE America, Inc.

Address: 845 Avenue G East
Arlington, Texas 76011

Contact Person: Thomas Dollar, Manager of Regulatory Affairs

The assigned 510(k) number is K003583.

Product Code: JII, Lithium Test Kit

Device Name: TRACE Lithium Reagent and Lithium Standard

Device Class: II

Predicate Device: AVL Electrolyte Analyzer

Description and Intended Use: TRACE's Lithium reagents are intended for the in vitro quantitative determination of Lithium (Li) in human serum or EDTA plasma.

Clinical Significance[1,2]: Lithium acts by enhancing the uptake of neurotransmitters, which produces a sedative effect on the central nervous system. Serum lithium concentrations are carried out essentially to ensure compliance and avoid toxicity.

Methodology[1]: Lithium concentrations can be determined by atomic absorption spectrophotometry, flame emission photometry, or ion selective electrode. The TRACE Lithium reagent is a spectrophotometric method, which can be adapted to automated clinical chemistry analyzers. Lithium present in the sample reacts with a substituted porphyrin compound at an alkaline pH, resulting in a change in absorbance, which is directly proportional to the concentration of Lithium in the sample.

Correlation: Comparison studies were carried out on an automated clinical chemistry analyzer (Hitachi 911) using a commercially available Lithium ISE analyzer (AVL Electrolyte Analyzer) as a reference. Serum samples were assayed in parallel and the results compared by the least regression method. The following statistics were obtained;

Number of Sample Pairs: 67
Range of Sample Results: 0.31-2.26 mmol/L
Mean of ISE Results: 0.85
Mean of TRACE Lithium results: 0.80
Slope: 0.95
Intercept: -0.02
Correlation Coefficient: 0.99

Imprecision:

Within Run

	Level 1	Level 2
Number of Data Points	80	80
Mean (mmol/L)	1.00	2.49
SD (mmol/L)	0.019	0.019
CV(%)	1.9	0.8

Total

	Level 1	Level 2
Number of Samples	80	80
Mean (mmol/L)	1.00	2.49
SD (mmol/L)	0.038	0.09
CV(%)	3.9	3.6

Conclusion: Analysis of the comparative measurements presented in the 510(k) submission for this device, together with linearity and precision data collected in data presented demonstrates the TRACE Lithium reagent is safe and effective. No significant differences exist between the results obtained on samples analyzed utilizing the TRACE Lithium reagent when compared to those obtained when utilizing the predicate device in these studies.

References: 1. Moyer TP and Pippenger CE. "Therapeutic Drug Monitoring" Tietz Textbook of Clinical Chemistry (Burtis CA and Ashwood ER Eds) Second Edition of WB Saunders Company.
2. Amdisen A. "Serum Lithium determinations for Clinical use" Scand Jnl Clin Lab Invest. 1967; 20: 104-8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 17 2001

Mr. Thomas Dollar
Manager of Regulatory Affairs
Trace America, Inc.
845 Avenue G East
Arlington, Texas 76011-7709

Re: K003583
Trade Name: TRACE Lithium Test System
Regulatory Class: II
Product Code: NDW
Dated: November 16, 2000
Received: November 20, 2000

Dear Mr. Dollar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Telephone 817/607-1700

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003583

Device Name: TRACE Lithium Test System

Indications For Use: These reagents are intended for the in vitro quantitative determination of Lithium (Li) in human serum or EDTA plasma. Measurements of Lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003583